

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

PERRIGO COMPANY, PERRIGO ISRAEL
PHARMACEUTICALS LTD. and PERRIGO
COMPANY OF SOUTH CAROLINA, INC.,

Plaintiffs,

v.

ABBVIE, INC., ABBOTT
LABORATORIES, UNIMED
PHARMACEUTICALS LLC, and BESINS
HEALTHCARE, INC.

Defendants.

CIVIL ACTION NO. _____

COMPLAINT

Plaintiffs Perrigo Company, Perrigo Israel Pharmaceuticals Ltd. and Perrigo Company of South Carolina, Inc. (“Perrigo”) bring this civil action against Defendants AbbVie, Inc., Abbott Laboratories, Unimed Pharmaceuticals, LLC (collectively “AbbVie”) and Besins Healthcare, Inc. (“Besins”) under the antitrust laws of the United States.

INTRODUCTION

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendants’ unlawful monopolization of a relevant market consisting of (a) topical testosterone replacement therapies or transdermal testosterone replacement therapies or (b) AndroGel 1% and AndroGel 1.62% and their AB-rated generic equivalents, through sham patent litigation against generic competitors, including Perrigo.

2. As Judge Harvey Bartle III of this Court found following a trial, Defendants’ sham patent litigation delayed Perrigo’s launch of its generic version of AndroGel 1%, AbbVie’s testosterone replacement product. But for Defendants’ unlawful conduct, Perrigo would have

launched its generic version of AndroGel 1% in June 2013 rather than on December 27, 2014 when Perrigo actually launched its generic version. *FTC v. AbbVie, Inc. et al.*, 329 F. Supp. 3d 98 (E.D.Pa. 2018), *appeal pending* Nos. 18-2621, 2748 and 2758 (3d Cir.).

3. As a result of Defendants' unlawful conduct, Perrigo lost sales, lost profits and lost the ability to market its version of AndroGel 1% before December 27, 2014. Perrigo has been injured in its business and property and brings this action to recover three-fold its actual damages and its cost of suit, including reasonable attorneys' fees.

PARTIES

4. Plaintiff Perrigo Company is a Michigan corporation having its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Perrigo Company manufactures and sells health care products, and through its affiliates and subsidiaries manufactured and sold testosterone gel, 1%, a generic version of AndroGel 1%, in the United States. Perrigo Company is a subsidiary of Perrigo Company plc, a company formed in December 2013 and incorporated under the laws of Ireland.

5. Plaintiff Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel"), is an Israeli corporation having its principal place of business at 1 Rakefet St., Shoham, 608500, Israel. At all times relevant to this Complaint, Perrigo Israel has been a subsidiary of Perrigo Company. Perrigo Israel develops, manufactures and markets generic pharmaceuticals. In 2011, Perrigo Israel submitted a New Drug Application under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act to the U.S. Food and Drug Administration ("FDA") for a generic version of AndroGel 1%. Perrigo Israel manufactured a generic version of AndroGel 1% for sale in the United States.

6. Plaintiff Perrigo Company of South Carolina, Inc. (“Perrigo S.C.”) is a Michigan corporation having its principal place of business at 515 Eastern Avenue, Allegan, MI 49010. At all relevant times, Perrigo S.C. has been a subsidiary of Perrigo Company. Perrigo S.C. sold Perrigo’s generic version of AndroGel 1% in the United States. Except where otherwise specified, as used in this Complaint, “Perrigo” includes Perrigo Company, Perrigo Israel and Perrigo S.C. and their relevant predecessors and successors-in-interest.

7. Defendant Abbott Laboratories (“Abbott”) is an Illinois corporation having its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott develops, manufactures and markets a variety of healthcare and pharmaceutical products in the United States. On January 1, 2013, Abbott completed the spinoff of AbbVie, Inc., a corporation formed to hold Abbott’s branded pharmaceutical business, including the marketing and sale of AndroGel 1% and AndroGel 1.62%. Before January 1, 2013, Abbott marketed AndroGel in the United States. Except where otherwise specified, “AndroGel” refers to AndroGel 1% (first sold in 2000) and AndroGel 1.62% (first sold in May 2011).

8. Defendant AbbVie, Inc. is a Delaware corporation having its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. Since January 1, 2013, AbbVie has been engaged in the manufacture, sale and distribution of branded pharmaceutical products, including AndroGel. AbbVie Products LLC f/k/a Abbott Products, Inc. f/k/a Solvay Pharmaceuticals, Inc. is currently a wholly owned subsidiary of AbbVie and was previously acquired by Abbott in 2010. In the twelve months ending December 31, 2013, AbbVie’s sales were approximately \$18.8 billion, and its U.S. sales of AndroGel exceeded \$1 billion. Except where otherwise specified, as used in this Complaint, “AbbVie” refers to AbbVie and relevant

predecessors and successors-in-interest, including Abbott Laboratories and Unimed (as defined below).

9. Defendant Unimed Pharmaceuticals, LLC f/k/a Unimed Pharmaceuticals, Inc. (“Unimed”) is a Delaware corporation and a wholly owned subsidiary of AbbVie with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. Solvay Pharmaceuticals, Inc. (“Solvay”) acquired Unimed in 1999 and Abbott acquired Solvay in 2010. Unimed developed and marketed AndroGel in the United States. As used in this Complaint, “Unimed” includes relevant predecessors and successors-in-interest.

10. Defendant Besins Healthcare, Inc. f/k/a Laboratoires Besins Iscovesco and Besins-Iscovesco US, Inc. (“Besins”) is a Delaware corporation with its principal place of business at 607 Herndon Parkway, Suite 210, Herndon, Virginia 20170. Besins is a wholly-owned subsidiary of Besins Healthcare, S.A. which is headquartered in Brussels, Belgium. Besins manufactures AndroGel for AbbVie under a license agreement. Besins’ employees, along with employees of Unimed, filed the patent application that led to the issuance of U.S. Patent No. 6,503,894 (“the ‘894 patent”) in 2003. As used in this Complaint, “Besins” includes relevant predecessors and successors-in-interest.

11. All of Defendants’ actions described in this Complaint were carried out by Defendants’ various officers, agents, employees, or other representatives within the course and scope of their duties and employment by Defendants, and/or with actual, apparent, and/or ostensible authority of Defendants.

JURISDICTION AND VENUE

12. This action is brought under section 2 of the Sherman Act, 15 U.S.C. §2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover treble damages and cost of suit,

including reasonable attorneys' fees, for the injuries sustained by Plaintiffs resulting from violations by Defendants of the antitrust laws alleged herein. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §15. The Court has personal jurisdiction over Defendants under 15 U.S.C. § 22.

13. Defendants transact business within this district. Therefore, venue is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

FACTUAL ALLEGATIONS

Regulatory Requirements for Approval of Drugs

14. The regulatory framework that governs the testing and approval of new drugs in the United States is governed by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, which is commonly known as the Hatch-Waxman Act, 21 U.S.C. § 355 and 35 U.S.C. § 271.

15. A drug manufacturer seeking to market a new drug must obtain approval from the FDA. *See* 21 U.S.C. § 355(a). There are three pathways established by the FDCA and Hatch-Waxman: (1) a section 505(b)(1) New Drug Application ("NDA"); (2) a section 505(b)(2) NDA; and (3) a section 505(j) Abbreviated New Drug Application ("ANDA").

16. An NDA is a full-length application containing information on the drug's safety and efficacy, an explanation of the drug's ingredients, a description of the methods used in the manufacture and packaging of the drug, and samples of the proposed labeling. *See* 21 U.S.C. § 355(b)(1). The NDA must also contain a list of any patent(s) that the NDA applicant asserts "claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be

asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” *Id.* Once the FDA approves the NDA, FDA then publishes this patent information in connection with the NDA drug in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book.”

17. Once the FDA has approved a new brand-name drug under an NDA, an applicant can seek approval of a generic version of that drug through the use of abbreviated procedures. *See* 21 U.S.C. § 355(j). Most commonly, the applicant will file a section 505(j) application, also known as an abbreviated new drug application or ANDA, stating, among other things, that the generic has the same active ingredients and is bioequivalent to the brand-name (or reference listed) drug. *Id.* § 355(j)(2)(A). The applicant may then rely on the safety and efficacy data contained in the NDA for the brand-name drug. *Id.*

18. In the alternative, the applicant for a generic drug may file a section 505(b)(2) NDA. A section 505(b)(2) NDA is used for generics that have certain modifications from the brand-name drug. *See* 21 C.F.R. § 314.54. The applicant must submit additional data to the FDA demonstrating that any differences between the brand-name drug and the generic will not affect safety and efficacy but can otherwise avoid the other studies necessary for a full NDA. *Id.*; *see also Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 227 (3d Cir. 2013). Because the Hatch-Waxman Act allows the applicant to rely on certain data and information provided in connection with the brand-name drug, its provisions “speed the introduction of low-cost generic drugs to market” and thereby promote drug competition. *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (alteration omitted)).

19. Once the FDA approves a generic drug, the applicant may request from the FDA a therapeutic equivalence (“TE”) rating. A TE rating is a code that reflects the FDA’s determination regarding whether a generic product is therapeutically equivalent to the reference-listed brand-name drug. Products that are determined to be therapeutically equivalent are generally assigned an “A” or “AB” rating. Generic products for which therapeutic equivalence cannot be determined are generally assigned a “B” or “BX” rating.

20. Every state in the United States has generic substitution laws. *See Mylan Pharm. Inc. v. Warner Chilcott*, 838 F.3d 421, 428 (3d Cir. 2018). These laws “either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written.” *Id.* (internal quotation marks and citations omitted). Thus, an “A” or “AB” rating generally permits automatic-generic substitution, where permitted by law.

21. The Hatch-Waxman Act also provides specialized procedures for parties to resolve intellectual property disputes. In submitting an ANDA or section 505(b)(2) NDA, an applicant must, with certain exceptions not applicable here, certify that any patent currently in force and listed in the FDA’s Orange Book for the referenced-listed brand-name drug “is invalid or will not be infringed by the manufacture, use, or sale” of the proposed generic, if the applicant desires to market its proposed generic prior to expiration of the patent. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 U.S.C. § 355(b)(2)(A)(iv). This certification is commonly referred to as a paragraph IV certification. *Actavis*, 570 U.S. at 143.

22. The ANDA or 505(b)(2) NDA applicant must give notice to the owner of the reference-listed drug and patent(s) that it has filed a paragraph IV certification with the FDA. 21 U.S.C. § 355(j)(2)(B); 21 U.S.C. § 355(b)(3). The notice often includes an offer of confidential

access whereby outside counsel for the patentee may review the application submitted to the FDA by the generic applicant to facilitate a determination regarding infringement litigation. If the patentee files an infringement suit against a generic entity within 45-days of its receipt of the paragraph IV notice, the FDA is generally required to withhold approval of the generic drug for 30 months from receipt of the paragraph IV notice or until the infringement action is resolved in the district court, whichever occurs first. 21 U.S.C. § 355(j)(5)(B)(iii).

23. Generic versions of brand name drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective, as their brand name counterparts. A material difference between bioequivalent generic and brand name drugs is their price. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission (“FTC”) estimates that, by one year after market entry, the generic version takes over 90% of the brand’s unit sales and sells for 15% of the price of the brand name product.

24. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for, and to compete with, the branded drug, and therefore the brand manufacturer can continue to profitably charge very high prices (relative to cost) without losing sales. As a result, brand manufacturers have a strong incentive to delay the introduction of generic competition into the market.

AndroGel

25. AndroGel is a brand-name transdermal testosterone gel product approved by the FDA for the treatment of hypogonadism, a clinical syndrome that results from failure of a man’s body to produce adequate amounts of testosterone. It is estimated that this condition affects 2-6% of the adult male population in the United States. Hypogonadism is a lifelong condition which

causes decreases in energy and libido, erectile dysfunction, and changes in body composition including decreased bone density. Patients with hypogonadism are typically treated with testosterone replacement therapy (“TRT”) whereby exogenous testosterone is administered.

26. The first TRTs approved by the FDA were injectables in which testosterone is dissolved in a liquid and then injected into a muscle of the body. Injectable testosterone were introduced in the 1950s and have been available in generic form for decades.

27. TRTs may also be administered through a gel or patch which is applied to the skin and thereby absorbed into the bloodstream. This group of products is known as topical testosterone replacement therapies or transdermal testosterone replacement therapies (“TTRTs”).

28. AndroGel 1% was launched in 2000 as the first FDA-approved testosterone gel. It is applied once a day to one or more application sites, including the upper arms, shoulders, and abdomen. AndroGel comes in two strengths: (1) 1%, which was the original formulation launched in June 2000; and (2) 1.62%, which was first sold in May 2011. At the time AndroGel 1% came on the market in 2000, it was available only in sachets. In 2004 it became available in a metered-dose pump. AbbVie discontinued manufacture of the AndroGel 1% pump in December 2013.

29. AndroGel 1% was developed through a collaboration between Unimed and various subsidiaries of Besins’ parent company. At the time of its launch in 2000, AndroGel 1% was marketed and distributed by Solvay, then the parent company of Unimed. Abbott Laboratories acquired Solvay and Unimed in February 2010. At that time, Solvay was renamed Abbott Products Inc. In January 2013, AbbVie assumed all of Abbott’s proprietary pharmaceutical business, including AndroGel 1%.

30. AndroGel's U.S. net annual sales were approximately \$604 million in 2009, \$726 million in 2010, \$874 million in 2011, \$1.15 billion in 2012, \$1.035 billion in 2013, and \$934 million in 2014. After entry of generic versions of AndroGel 1%, AndroGel U.S. net sales fell to \$694 million in 2015.

31. In or about 2003, the '894 patent was listed in the FDA's Orange Book for AndroGel 1%. That patent is owned by Besins and by Unimed. Unimed was a wholly-owned subsidiary of Solvay until 2010. Laboratoires Besins Iscovesco SA, a subsidiary ultimately owned by Besins' parent company and now known as Laboratoires Besins Iscovesco SAS ("LBI SAS"), licensed to Unimed certain intellectual property rights to AndroGel. In return, Unimed was obligated to pay a royalty on net sales of AndroGel. Under a separate supply agreement, LBI SAS agreed to manufacture and sell to Unimed AndroGel products for sale and distribution by Unimed in the United States.

The '894 Patent

32. The initial patent application that resulted in the '894 patent claimed a pharmaceutical composition of a testosterone gel including a penetration enhancer, which according to the patent application "is an agent known to accelerate the delivery of the drug through the skin into the bloodstream." *FTC v. AbbVie*, 2017 WL 4098668 (E.D. Pa. Sept. 15, 2017) at *1-2. "Claim 1 [of the patent application] encompassed all penetration enhancers without limitation" which included isopropyl myristate, the penetration enhancer actually used in AndroGel 1%. *Id.* at *2.

33. The patent examiner at the U.S. Patent and Trademark Office ("PTO") rejected the claim which included all penetration enhancers. Thereafter, Unimed and Besins submitted an

amendment narrowing their claim encompassing all penetration enhancers to a claim naming only twenty-four specific penetration enhancers, including isopropyl myristate. *Id.* at *2-3.

34. After a series of additional amendments, Unimed and Besins further narrowed their claim to one penetration enhancer only: isopropyl myristate. *Id.* at *3. On this basis, the '894 patent was issued on January 7, 2003. *Id.* at *4.

Perrigo ANDAs for AndroGel 1%

35. Generic manufacturers sought entry into the market to compete with AndroGel 1%. In December 2008, Perrigo submitted to the FDA two ANDAs for a generic testosterone 1% gel, one for the pump and one for the packet form. The ANDAs referenced AndroGel 1% and contained the paragraph IV certification to the '894 patent. However, the Perrigo product contained isostearic acid as its penetration enhancer rather than isopropyl myristate claimed in the '894 patent.

36. Pursuant to the procedures established by the Hatch-Waxman Act, Perrigo in June 2009 served paragraph IV notices on both Unimed and Besins as co-owners of the '894 patent. In those notices, Perrigo disclosed the filing of its ANDAs for a generic 1% testosterone gel. Perrigo further asserted, among other things, that its ANDA products would not literally infringe the '894 patent for AndroGel 1% because the Perrigo products did not contain “about 0.1% to about 5% isopropyl myristate,” the sole penetration enhancer formulation claimed in the patent. Perrigo also stated in its notices that the prosecution history of the '894 patent would estop Unimed and Besins from asserting patent infringement under the doctrine of equivalents. Finally, Perrigo offered to provide to outside counsel representing Unimed and Besins confidential access to the full ANDAs so that Unimed and Besins could confirm that Perrigo's ANDA products do not infringe the '894 patent.

37. Thereafter Unimed and Besins, along with Unimed's parent Solvay, jointly retained the law firm of Finnegan, Henderson, Farabow, Garrett and Dunner, LLP ("Finnegan, Henderson") to assess the Perrigo paragraph IV notices and the Perrigo ANDAs. Finnegan, Henderson obtained confidential access to the full ANDAs and confirmed that Perrigo's ANDAs contained isostearic acid, not isopropyl myristate. Besins also separately retained the law firm of Foley and Lardner LLP ("Foley and Lardner"). Foley and Lardner did not receive confidential access to the ANDAs.

38. On July 17, 2009, Solvay and Unimed issued a press release announcing that "[a]fter careful evaluation" the companies had decided not to file a patent infringement suit against Perrigo. The press release explained that the Perrigo product "contains a different formulation than the formulation protected by the AndroGel patent." It further stated that "[t]his distinction played a role in the company's decision not to file patent infringement litigation at this time" but "the company does not waive its right to initiate patent infringement litigation at a later stage based on new or additional facts and circumstances." Besins also determined that it was "standing down" from bringing an infringement suit but did not join in the Solvay press release or issue its own public announcement.

FDA Changed Requirements

39. Sometime in 2009, the FDA became aware of cases of accidental secondary exposure of children to TTRTs due to skin-to-skin transference from patients using these products. Based on this information, the FDA required safety-related labeling changes and a Risk Evaluation and Mitigation Strategy for transdermal testosterone gel products currently on the market.

40. On August 26, 2009, the FDA directed that any application for a generic testosterone gel product containing a penetration enhancer different from the referenced brand-name drug would be required to be submitted as a section 505(b)(2) NDA rather than an ANDA. The application must also include certain additional safety studies regarding the risk of secondary exposure.

41. On April 9, 2010, AbbVie, now the owner of AndroGel 1%, filed a citizen petition with the FDA. The FDA permits private entities to petition the Agency to take particular regulatory or administrative action by filing citizen petitions. 21 C.F.R. § 10.30. A petition can request that the FDA “issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action.” *Id.*

42. In its citizen petition, AbbVie noted the FDA’s ruling regarding all generic testosterone products containing penetration enhancers different than those contained in the reference-listed brand-name drug. AbbVie sought assurance from the FDA that Perrigo would be required to resubmit its ANDAs referencing AndroGel 1% as section 505(b)(2) NDAs. AbbVie also requested that Perrigo be directed to provide to the AndroGel 1% patent holders a new paragraph IV notice. Finally, it asked that Perrigo be required to conduct transfer and hand-washing studies.

43. On October 4, 2010, the FDA granted in part and denied in part AbbVie’s citizen petition. The FDA directed that any application by a generic manufacturer for a product referencing AndroGel 1% that contained a different penetration enhancer must be submitted as a section 505(b)(2) NDA. It also agreed that the applicants would be required to submit new paragraph IV notices.

Defendants' Patent Litigation Against Teva

44. On January 13, 2011, Teva Pharmaceuticals USA, Inc. ("Teva") filed a section 505(b)(2) NDA for its generic version of AndroGel 1% which described a different penetration enhancer, isopropyl palmitate, than AbbVie used in its brand-name AndroGel 1%. The application sought approval to manufacture and to distribute the product in two different sachet sizes as well as in pump form.

45. On March 16, 2011, Teva sent to Solvay, AbbVie, Unimed, and Besins a paragraph IV notice regarding its section 505(b)(2) NDA. Teva asserted that its product did not infringe the '894 patent because "the Teva formulation does not contain isopropyl myristate," the penetration enhancer claimed in the '894 patent. Teva laid out the prosecution history of the '894 patent and its position that, because the claims of the '894 patent were narrowed to disclose only isopropyl myristate, "the prosecution history estops the patentees from asserting infringement under the doctrine of equivalents." Teva also offered confidential access to certain information regarding its section 505(b)(2) NDA to allow the patent holders to assess whether an infringement action would have merit.

46. AbbVie retained outside counsel at the law firm of Munger, Tolles and Olson LLP ("Munger Tolles") to evaluate the Teva paragraph IV notice. Munger Tolles was provided with access to the Teva section 505(b)(2) NDA and provided in-house counsel at AbbVie with its opinion. Besins again retained Foley and Lardner to evaluate the notice. The Foley and Lardner firm was supplied with confidential access to the NDA and submitted its analysis to Besins.

47. On April 29, 2011, within 45 days after receiving the paragraph IV notice, AbbVie, Unimed, and Besins commenced an action in the U.S. District Court for the District of

Delaware alleging that Teva's product infringed the '894 patent. *See Abbott Prods., Inc. v. Teva Pharm. USA, Inc.*, No. 11-384, 2011 WL 1765168 (D. Del. Apr. 29, 2011). The suit against Teva triggered the Hatch-Waxman automatic stay of FDA approval of the Teva product.

Consequently, the FDA could not approve Teva's generic testosterone drug for 30 months after March 16, 2011 or until September 17, 2013 unless a district court ruling or a settlement resolved the lawsuit sooner.

48. The intellectual property ("IP") litigation group at AbbVie had direct accountability for patent litigation. Four in-house patent attorneys in that group had final responsibility for evaluating the Teva paragraph IV notice and made the decision to file the patent infringement suit against Teva: (1) Johanna Corbin; (2) Adam Chiss; (3) Anat Hakim; and (4) Jose Rivera. All of these attorneys had extensive experience in patent law and with AbbVie. During the relevant time period, Johanna Corbin was vice president of the IP group and the lead IP attorney at AbbVie who worked in that group since 2005. Adam Chiss was divisional vice president of IP litigation and before that had served as senior counsel in IP litigation. Anat Hakim was divisional vice president and associate general counsel of IP litigation at AbbVie and previously had been a partner at Foley and Lardner. Finally, Jose Rivera was a divisional vice president of the IP group and had previously worked in private practice. The general counsel of AbbVie, Laura Schumacher, also signed off on the final decision. Schumacher had been with AbbVie or its predecessor since 1990.

49. As for Besins, the decision to sue was made by Thomas MacAllister, its in-house counsel. MacAllister is an experienced intellectual property attorney who previously worked as a patent examiner at the U.S. Patent and Trademark Office. Besins conferred with outside counsel as well as AbbVie about the Teva product and potential litigation. Like AbbVie, Besins or its

agents had confidential access to the portions of Teva's NDA that disclosed the formulation of its product prior to filing the complaint against Teva. In addition, in-house counsel for Besins conferred with in-house counsel for AbbVie before making the decision to initiate the lawsuit.

50. Around this time AbbVie also was preparing for FDA approval and launch of its low-volume formulation of AndroGel, known as AndroGel 1.62%. The FDA issued final approval of brand-name AndroGel 1.62% on April 29, 2011, and AbbVie began selling it in May 2011. The 1.62% formulation is indicated for the same condition and has the same active ingredient but less total gel due to its greater concentration of active ingredient. By the last seven months of 2012, sales of AndroGel 1.62% accounted for 57% of total AndroGel sales, 67% in 2013, 76% in 2014, and 83% in 2015.

51. On August 1, 2011, before discovery had commenced, Teva filed a motion for summary judgment in the patent infringement suit in the District of Delaware. Teva asserted that based on prosecution history estoppel there could be no viable claim of infringement of the '894 patent. Instead of ruling on the Teva motion, on October 25, 2011, the court set trial on the issue of prosecution history estoppel for May 21, 2012.

Defendants' Patent Litigation Against Perrigo

52. On July 4, 2011, Perrigo re-filed with the FDA its application for approval of a generic testosterone 1% gel as a section 505(b)(2) NDA. The Perrigo formulation was substantially the same as the one for which it submitted its ANDAs in 2008, including use of the same penetration enhancer as in its 2008 ANDAs.

53. On September 20, 2011, Perrigo sent AbbVie, Unimed, and Besins a new paragraph IV notice. As in its 2009 notice, Perrigo certified that the '894 patent was not infringed because its generic testosterone product did not contain "about 0.1% to 0.5% isopropyl

myristate,” the penetration enhancer claimed in the patent.

54. Perrigo’s notice letter also explained that the prosecution history of the ’894 patent precluded any valid infringement claim under the doctrine of equivalents. Perrigo offered and provided confidential access to certain information regarding the NDA so that AbbVie and Besins could confirm that the Perrigo product does not infringe the ’894 patent. Again, AbbVie and Unimed retained Munger Tolles as outside counsel to analyze Perrigo’s NDA and the firm provided its analysis to AbbVie. Foley and Lardner evaluated Perrigo’s NDA on behalf of Besins and also provided its analysis to Besins.

55. On October 31, 2011, AbbVie, Unimed, and Besins filed suit in the United States District Court for the District of New Jersey alleging that Perrigo’s 1% testosterone gel infringed the ’894 patent. *See Abbott Prods., Inc. v. Perrigo Co.*, No. 11-6357, 2011 WL 5314659 (D.N.J. Oct. 31, 2011). As in the Teva litigation, the filing of the complaint against Perrigo triggered an automatic 30-month stay under the Hatch-Waxman Act. Thus, absent a court ruling or settlement resolving the litigation, the stay would preclude final FDA approval of the Perrigo generic testosterone product until on or about March 20, 2014.

56. The same four AbbVie in-house attorneys who made the decision to sue Teva made the decision to file the suit against Perrigo with approval from the same general counsel. They conferred with outside counsel, who had confidential access to the Perrigo section 505(b)(2) NDA. After consultation with AbbVie and outside counsel, Besins’ same in-house attorney made the decision that it would join in bringing the Perrigo litigation.

Settlement of the ‘894 Patent Litigation

57. AbbVie reached out to Teva to discuss an amicable resolution of the dispute before the complaint was filed in April 2011. Perry Siatis, an in-house attorney for AbbVie, was

the main negotiator on behalf of AbbVie. At that time, Siatis was Divisional Vice President of the IP strategy group and head intellectual property attorney at AbbVie. Although that initial contact did not lead to a settlement, AbbVie again raised the subject with Teva during an in-person meeting on October 28, 2011, three days after the court in the Teva litigation had set a trial date. On December 20, 2011 the parties reached a final settlement in the Teva litigation, in which Teva received a license to launch its product beginning December 27, 2014.

58. On November 3, 2011, Siatis approached Perrigo to initiate settlement negotiations in the Perrigo litigation. On December 8, 2011 the parties executed a binding term sheet, which included the dismissal of claims. In addition, AbbVie agreed to pay Perrigo \$2 million dollars as reasonable litigation expenses.

59. During the negotiations Perrigo pushed for an earlier entry date but was unsuccessful and ultimately accepted an offer from Defendants of January 1, 2015. However, the settlement contained an acceleration clause and most favored nations (“MFN”) protection whereby Perrigo would be permitted to launch if another generic came to market or if Defendants entered an agreement with another generic providing an entry date more favorable than the date applicable to Perrigo.

60. Perrigo was unaware of the Teva settlement negotiations when it negotiated and executed the December 8, 2011 binding term sheet.

61. As a result of the Teva settlement, Perrigo’s licensed entry date was moved up to December 27, 2014 under the MFN provision.

FDA Approval of Teva’s and Perrigo’s NDAs for AndroGel 1%

62. On February 14, 2012, the FDA approved Teva’s section 505(b)(2) NDA for the packet presentation of its TTRT product. After receiving FDA approval, Teva waited for the

FDA Office of Generic Drugs to assign a TE rating for its product. Teva did not receive an AB rating for its product when the FDA issued a rating in July 2014. Teva decided not to launch its generic AndroGel 1% product on the date permitted in its settlement agreement, *i.e.*, December 27, 2014 or thereafter.

63. On January 31, 2013, the FDA approved Perrigo's section 505(b)(2) NDA for its generic version of AndroGel 1%. The FDA did not provide a TE rating in the January 31, 2013 approval letter.

64. As its December 27, 2014 licensed entry date approached, Perrigo took a number of steps to follow up with the FDA regarding its TE rating. Perrigo sent three letters to the FDA between April 2013 and February 2014 requesting that the FDA issue an AB rating. It received no response other than being informed that the FDA needed more time to evaluate the therapeutic equivalence of the product.

65. Perrigo filed a lawsuit against the FDA in the United States District Court for the District of Columbia on March 21, 2014. *See Perrigo Israel Pharm. Ltd. v. U.S. Food & Drug Admin.*, No. 14-475 (D.D.C. Mar. 21, 2014). Perrigo asserted that the FDA had engaged in unreasonable delay. It requested that the court enter a mandatory injunction compelling the FDA to publish a TE rating for Perrigo's NDA product as soon as possible. On April 10, 2014, the FDA filed its response to the lawsuit. The FDA contended that "Perrigo has itself obviated the need for a prompt decision by reaching an agreement with the innovator not to market until December 2014." The FDA further represented that it expected to issue a TE rating for Perrigo's product "by July 31, 2014—fully five months before Perrigo's planned product launch."

66. Prior to the deadline, on July 23, 2014, the FDA determined that Perrigo's section 505(b)(2) NDA product was therapeutically equivalent to AndroGel 1% and issued it an AB rating.

67. Perrigo launched its AB-rated generic version of AndroGel 1% on December 27, 2014, its licensed entry date under the settlement agreement with Defendants.

68. But for Defendants' anticompetitive conduct alleged above, Perrigo would have received its AB rating in June 2013 rather than July 2014 and would have launched its AB-rated product at that time rather than on December 27, 2014.

Objective and Subjective Baselessness of Defendants' '894 Patent Litigation

69. The patent lawsuits brought against both Teva and Perrigo in 2011 were objectively baseless. As noted above, Unimed and Besins obtained the '894 patent only by narrowing the initial broad claim in their patent application covering all penetration enhancers to a very limited claim covering only a single penetration enhancer, isopropyl myristate, at a particular concentration. *FTC v. AbbVie*, 2017 WL 4098668 (E.D. Pa. Sept. 15, 2017).

70. Neither the Teva product nor the Perrigo product contained the penetration enhancer isopropyl myristate, the only penetration enhancer claimed in the '894 patent. Instead of isopropyl myristate, Teva used isopropyl palmitate and Perrigo used isostearic acid as a penetration enhancer in their generic versions of AndroGel 1%.

71. One purpose of prosecution history estoppel is to protect competitors of the patentee from liability for patent infringement under the doctrine of equivalents if the prosecution history shows that a potential equivalent not specifically disclosed in the patent has been purposely and not tangentially excluded from the scope of the patent. That is exactly what occurred here. AbbVie and Besins purposely excluded all penetration enhancers other than

isopropyl myristate during prosecution in order to convince the patent examiner to issue the patent. AbbVie and Besins could not purposely surrender claims to all penetration enhancers except one in order to obtain the patent in the first instance and then claim infringement when a competitor used an enhancer that they had deliberately surrendered. No reasonable person in Defendants' position could have realistically expected to prevail on the merits of their patent infringement claims against Teva and Perrigo.

72. The patent litigation against Perrigo and Teva was also subjectively baseless. Defendants AbbVie and Besins had actual knowledge that the patent infringement suits were baseless and destined to fail. They filed those suits only for the purpose of delaying Teva's and Perrigo's entry into the market as competitors with lower price generics, not with any expectation of actually winning either case.

73. As noted above, Solvay issued a press release in 2009 announcing the company's decision not to sue Perrigo for infringement of the '894 patent because the Perrigo product "contain[ed] a different formulation than the formulation protected by the AndroGel patent." Besins also decided to "stand down" from pursuing Perrigo for infringement. The facts supporting both companies' decision not to pursue Perrigo for infringement did not change between 2009 and 2011, when the companies changed their minds and filed suit.

74. The individuals who made the decision on AbbVie's behalf to file objectively baseless lawsuits against Perrigo and Teva were four experienced patent attorneys who had sign-off from AbbVie's general counsel. Besins' decision to sue was likewise made by an experienced patent attorney.

75. The decision-makers at both companies were aware of the paragraph IV notices sent by Perrigo and Teva, which made it clear that their respective products did not contain the

single penetration enhancer claimed in the '894 patent. Outside counsel for AbbVie and Besins had confidential access to the section 505(b)(2) NDAs of Perrigo and Teva, which identified the penetration enhancers used by Perrigo and Teva, and were able to confirm the representations made in the paragraph IV notices. Both paragraph IV notices reviewed the prosecution history of the '894 patent and called to the attention of the decision-makers that any infringement actions by Defendants would be barred by prosecution history estoppel.

76. The experienced patent attorneys at both companies knew the law concerning the prosecution history estoppel and related principles and understood that prosecution history estoppel barred the infringement suits against Perrigo and Teva.

77. The decision-makers at AbbVie and Besins were also aware that AndroGel was bringing in hundreds of millions of dollars in sales every year as of 2011 at very high profit margins. Sales of AndroGel 1% were \$604 million and \$726 million, in 2009 and 2010, respectively, and sales of AndroGel 1% and 1.62% were \$874 million in 2011. The decision-makers were aware that the entry of generic versions of AndroGel, with their much lower prices, would quickly and significantly erode these sales. Their decision to file objectively baseless lawsuits against their generic competitors was based on a desire to staunch, at least for a time, this looming financial reversal.

78. Because these decision-makers filed objectively baseless infringement lawsuits, it is reasonable to conclude that they intended the natural and probable consequences of acts they knowingly did. This leads ineluctably to an inference that the subjective intent of the decision-makers was to file sham lawsuits.

Market Power and Relevant Market

79. By their anticompetitive conduct of filing sham litigation and delaying the entry of much less expensive competitive generic products, Defendants were able to maintain monopoly power in a relevant product market in the United States consisting of the sale of (a) TTRTs or (b) AndroGel 1% and AndroGel 1.62% and their AB-rated generic equivalents.

80. As Judge Bartle found, transdermal testosterone replacement therapies, or topical testosterone replacement therapies (TTRTs), are a relevant antitrust product market based on both reasonable interchangeability and cross-elasticity of demand. There is little cross-elasticity of demand between TTRTs and injectables. Injectables have been on the market for many years and are available at a fraction of the cost of AndroGel and other TTRTs, yet have not taken significant sales away from TTRTs. *FTC v. AbbVie*, 329 F. Supp. 3d 98, 131-134 (E.D. Pa. 2018).

81. AndroGel's share of the TTRT market was 71.5% at the time that the first sham lawsuit against Teva was filed in April 2011 and 63.6% at the time that the sham lawsuit against Perrigo was filed at the end of October 2011. Thereafter AndroGel's share remained above 60% until the end of 2014, when Perrigo's generic 1% testosterone product entered the market. The closest competitor, Testim, had a share of only approximately 20% of the TTRT market at the time of the filing of the first sham lawsuit, but thereafter its share dropped to approximately 12%. Axiron was launched on March 28, 2011 and had captured approximately 14% of the TTRT market by April 2014. No other TTRT product ever held 10% or more of the market during the period from April 2, 2011 through the end of 2014. AbbVie was able to maintain its share of the TTRT market with a profit margin of more than 65% during the relevant period, even after accounting for rebates. It was also able to increase the wholesale acquisition cost for AndroGel

throughout this time period. Accordingly, AndroGel had a dominant share of the TTRT market from April 2011 through December 2014. *FTC v. AbbVie*, 329 F. Supp. 3d 98, 134-135 (E.D. Pa. 2018).

82. Defendants' monopoly power is further supported by the existence of significant barriers to entry into the TTRT market. Any prospective entrant into the TTRT market must invest large amounts of time and capital in research and development. In addition, there are significant technical and regulatory requirements in the pharmaceutical business that do not exist with respect to ordinary consumer products. Branded drugs must be approved by the FDA through the submission of an NDA, and approval of an NDA can be a lengthy and expensive process.

83. Even after a branded drug is approved, brand-name drug companies face significant barriers in attempting to convince physicians to prescribe the product, which typically involves the use of a trained and knowledgeable sales force. The sale and marketing of prescription drugs is itself highly regulated. *See generally* 21 U.S.C. § 331. Sales representatives are not permitted to promote the drug for uses other than those approved by the FDA. The company must also ensure that pharmacies will stock the drug and that third-party payors will reimburse for it. This requires a team of skilled employees who can negotiate contracts with insurance companies and other payors. If the company seeks patent protection, which is routine, it must embark on the patent approval process before the Patent and Trademark Office.

84. While the Hatch-Waxman Act provides streamlined procedures for the approval of generic products through the filing of an ANDA or section 505(b)(2) NDA, the FDA may ask for additional information and testing as happened here with Perrigo and Teva. The drug once approved must undergo a further process before a different group at the FDA to obtain a TE

rating so that the generic drug developer may take advantage of state automatic-substitution laws. Again, Teva and Perrigo both confronted this hurdle.

85. There can be additional obstacles for generic drug companies where, as here, a brand-name drug manufacturer holds a patent listed for the reference-listed drug. Generic entrants must also consider the possibility of patent infringement litigation by the owner of the referenced brand-name drug and the accompanying delay caused by the automatic thirty-month stay under the Hatch-Waxman Act before entry into the market, as occurred here.

86. As an alternative to the TTRT product market definition, the relevant product market in this case is AndroGel 1% and AndroGel 1.62% and their AB-rated generic equivalents as proposed by the FTC. Defendants held 100% of sales in this product market until entry of Perrigo's generic AndroGel 1% product. *FTC v. AbbVie*, 329 F. Supp. 3d 98, 128-129 (E.D. Pa. 2018).

87. The relevant geographic market is the United States.

Interstate Commerce

88. At all material times, the AndroGel product at issue in this case was sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

Effect on and Injury to Competition and to Perrigo

89. Defendants' anticompetitive conduct outlined in this Complaint had the purpose and effect of restraining competition unreasonably and injuring competition by delaying the entry of Perrigo's generic version of AndroGel 1% and protecting branded AndroGel from generic competition. Generic competition would have resulted in a lower-priced generic AndroGel 1% being on the market.

90. But for Defendants' unlawful monopolization alleged above, Perrigo would have launched and sold an AB-rated generic version of AndroGel 1% in June 2013 rather than on December 27, 2014, when Perrigo actually launched and began selling its generic version of AndroGel 1%.

91. Defendants' unlawful monopolization delayed entry of Perrigo's lower cost generic version of AndroGel 1% into the United States market causing injury to competition and consumers.

92. As a result of Defendants' unlawful monopolization, Perrigo has lost sales, lost profits and the ability to market its version of AndroGel 1%. Perrigo has been injured in its business and property and brings this action to recover three-fold its actual damages and its cost of suit, including reasonable attorneys' fees.

FTC Litigation Against Defendants

93. The Federal Trade Commission ("FTC") brought an action against the same Defendants in this case entitled *FTC v. AbbVie, Inc. et al.*, Civil Action No. 14-5151 (E.D. Pa.) (the "FTC case"), *see* 2017 WL 4098668 (E.D. Pa. Sept. 15, 2017) (partial summary judgment on objective baselessness) and 329 F. Supp. 3d 98 (E.D.Pa. 2018) (Findings of Fact and Conclusions of Law) *appeal pending* Nos. 18-2621, 2748 and 2758 (3d Cir.). Each Defendant herein was a defendant in the FTC case and had a full and fair opportunity to litigate the facts found by Judge Bartle, including during a three-week nonjury trial.

94. The filing of the FTC case has tolled the statute of limitations applicable to Plaintiffs' claims from the date the FTC case was filed (September 8, 2014) through the date of the filing of this Complaint. 15 U.S.C. § 16(i).

CLAIM FOR RELIEF

**VIOLATION OF 15 U.S.C. § 2 - MONOPOLIZATION
AGAINST ALL DEFENDANTS**

95. Plaintiffs incorporate by reference the foregoing allegations as though fully set forth herein.

96. At all relevant times, Defendants possessed monopoly power in the relevant market.

97. Through their sham litigation against Perrigo, as set forth above, Defendants have willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by competing on the merits, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

98. Defendants' conduct has substantially harmed competition in the relevant market by delaying and/or minimizing the success of competition from a generic version of AndroGel 1% thereby enabling Defendants to continue to charge higher prices for AndroGel 1% than they would have had lower priced generic AndroGel 1% been available earlier.

99. There is and was no cognizable procompetitive justification for Defendants' actions.

100. As a direct and proximate result of Defendants' monopolization, as alleged herein, Plaintiffs have suffered injury to their business and property in the form of lost sales and lost profits.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

- A. Enter judgment in favor of Plaintiffs and against Defendants;
- B. Declare that Defendants' conduct alleged in this Complaint is in violation of Section 2 of the Sherman Act, 15 U.S.C. §2;
- C. Award Plaintiffs damages, in an amount to be determined at trial, trebled;
- D. Award Plaintiffs their cost of suit, including reasonable attorneys' fees as provided by law; and
- E. Award such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ Nicholas M. Centrella

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